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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,205	12/10/2001	Christa Tauer	V-258.00	9038
7590 03/24/2004 Baxter Healthcare Corporation P.O. Box 15210 Irvine, CA 92614			EXAMINER LI, BAO Q	
			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,205

Applicant(s)

TAUER ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Decemer 12, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7,8,10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7, 8, 10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 4, 9-11 and 14 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson et al. (US Patent SN. 5,268,292A), Provost et al. (US Patent No. 4,783,407), Kistner et al. et al. (WO 96/15231A2), Cinatl Jr. et al. (Biology International 1993, Vol. 17, No. 9, pp. 885-895) and Kuzuhara et al. (EP 0 339 667B1) on the same ground as stated in the previous Office Action.

3. Applicants traverse the rejection and submit that the extent that the rejection applied to the claim as amended. Because neither Robertson et al. nor Kuzuhara et al teach a method of producing complete HAV particles in VERO cells, wherein filtering is implied to remove impurity to obtain a purified preparation of complete HAV particles in a single step.

4. Applicants' argument has been respectfully considered; however, it is not found persuasive because the limitation of producing HAV particles in Vero cells has been taught by Provost et al and Kistner et al. Moreover, they also disclose that the use of Vero cell has great advantage over other cells. For instance, Provost et al. explicitly teach a method for using Vero cell to grow HAV, and they also disclose that the use of Vero cell has great advantage over other acceptable cell lines because Vero cells are available in large quantities and more readily adaptable to large scale cell culture technique than MRC-5 cells since the transformed Vero cell line has an infinity lifetime and will always be adequate for large-scale vaccine manufacture (See examples 1 and 2 on col. 3 & 4 and lines 34-45 on col. 1 and). Kistner et al. disclosed that Vero cell line is licensed by WHO for general vaccine production and it susceptible for growing many viruses, including HAV in the serum and protein free medium (Claims 1-4). In addition, Kistner et al. further point out that the advantage of using serum free medium is to overcome the problem of lacking batch-to-batch consistency, and undesired contaminations by using the serum

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containing medium that complicates the viral production and purification process (See lines 32 on page 11 through line 5 on page 12). Therefore, it would have been motivated to let any person with ordinary skill in the art to take the advantage of using the Vero cells for propagating the HAV virus.

5. Regarding to the amendment of last step of filtering, Applicants asserted that this is a single step of filtration, and no prior art teach that they use it as a single step.

6. Applicants' argument has been fully considered; however, it is not found persuasive because according to the disclosure of the specification, the last step of the purification is not only filtering, it is a diafiltration, which is a combination step of filtering plus dialyzation (See specification page 21-22). Robertson et al. teach the final procedure of purification of the enzyme treated HAV particles after concentration is to use a Centriflo cone filter unit to filter and dialyze the isolated HAV particle at the same time (See lines 25-28 on col. 6). Therefore, it is also a diafiltration step.

7. Hence, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0906. The examiner can normally be reached on 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
Art Unit 1648
March 16, 2004


JAMES HOUSEL 3/22/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600